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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/028,258   | 12/19/2001  | Celal Albayrak       | 0081.02             | 2329             |
| 21968  | 7590        | 04/21/2004           | EXAMINER            |                  |
| NEKTAR THERAPEUTICS<br>150 INDUSTRIAL ROAD<br>SAN CARLOS, CA 94070 |             |                      |                     | WELLS, LAUREN Q  |
|  |             | ART UNIT             |                     | PAPER NUMBER     |
|  |             | 1617                 |                     |                  |

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |                 |  |
|------------------------------|-----------------|-----------------|--|
| <b>Office Action Summary</b> | Application No. | Applicant(s)    |  |
|                              | 10/028,258      | ALBAYRAK, CELAL |  |
|                              | Examiner        | Art Unit        |  |
|                              | Lauren Q Wells  | 1617            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 22 December 2003.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-30 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

## **DETAILED ACTION**

Claims 1-30 are pending. The Amendment filed 12/22/03, amended claim 1.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-30 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added recitation in instant independent claim 1, "selected such that the volume fraction of the surfactant phase is at least 0.6" is new and does not have support in the original disclosure.

### ***112 Rejection Maintained***

The rejection of claim 22 under 35 U.S.C. 112 is MAINTAINED for the reasons set forth in the Office Action mailed 6/24/03.

Applicant has neither amended claim 22 or provided arguments against this rejection. Thus, this rejection is maintained for reasons of record.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-17, 20-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rossling et al. (WO 97/19676).

The instant invention is directed toward a process of making microparticles comprising dissolving a polymer in a halogen free solvent that partially water miscible, adding a hydrophilic active agent, mixing the two, and adding an aqueous aqueous surfactant and mixing.

Rossling et al. teach a method of producing morphologically uniform microcapsules. The method comprising dissolving biodegradable polymers in a halogen-free solvent or solvent mixture, and then dispersing into this solution, a buffered, hydrophilic active ingredient solution. Then, an aqueous solution that contains a surface-active substance is added to the emulsion, and the solvent is removed by vacuum. The microcapsules are taught as ranging in size from 200nm to 500um. Polyglycolides, such as glycolide/lactide copolymers are taught as polymers. Acetone, ethanol, alkyl acetates, alkyl formates, triacetin, triethyl citrate, and/or alkyl lactates are taught as solvents. Tris(hydroxymethyl)aminomethane and citrate are taught as buffer solutions. Nonionic surfactants, polyethylene glycol, and others are taught as surfactants. The reference does not teach the solubility parameters of the polymer solvent and the aqueous phase as less than zero and does not teach the preferred ratios of the polymer phase to the surfactant phase, and the volume fraction of the surfactant phase. US 6,294,204 relied upon as an English translation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the solubility parameters, ratios, and volumes of the polymer solvent and the aqueous phase of Rossling et al. because it has been held that where the general conditions of

a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Thus, one of skill in the art would be motivated to vary these parameters because of the expectation of achieving the most stable product, wherein the active ingredient is most efficiently and effectively delivered.

The Examiner respectfully points out instant claim 30 is a product-by-process claim. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113. However, since claim 30 depends on claims 1, 5, 8, 24 or 26, claim 30 is not being rejected under 102(b), though such microparticles are known in the art.

Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rossling et al. as applied to claims 1-17 and 20-30 above, and further in view of Setterstrom et al. (6,410,056).

Rossling et al. is applied as discussed above. The reference lacks microspheres and microsponges.

Setterstrom et al. teach that microspheres tend to be more difficult to rupture as compared to microcapsules because of their internal structure is stronger. Microsponges are taught as porous microspheres. See Col. 3, lines 44-56.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the microparticles of Rossling et al. into microspheres instead of

microcapsules because of the expectation of achieving a formulation that is stronger and does not rupture as easily, thereby producing a formulation that is longer-lasting once ingested.

***Response to Arguments***

Applicant argues, “there is nothing in Rossling to suggest the optimal solubility parameters of the polymer solvent and the aqueous surfactant phase. Further, Rossling does not suggest a high volume fraction of surfactant phase”. This argument is not persuasive. It is respectfully pointed out that Rossling et al. teach in their independent claim 1, thereby providing a final total volume wherein the polymer/active agent dispersion is present in the total volume in an amount less than 50% v/v, and the surfactant solution is present in the total volume in an amount less than 60% v/v. Thus, it would be within the skill of the artisan in the microparticle art to optimize the volumes, and hence, solubility parameters, to achieve that recited in the instant claims. It is respectfully pointed out that it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Furthermore, it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Applicant argues, “Rossling’s examples, and in fact the claims, describe fractions below 0.6. Further, Rossling describes a large variety of possible polymer solvents and surfactant phases and gives no guidance to the miscibility of the polymer solvent in the aqueous surfactant phase”. This argument is not persuasive. First, it is respectfully pointed out that Rossling specifically teach in their independent claim 1 a polymer solution in a partially water miscible halogen-free solvent. Second, this argument is not commensurate in scope with the instant

independent claims, which do not recite specific polymer solvents or surfactants. Additionally, Rossling et al. teach the same polymer solvents and surfactants as those taught in the instant dependent claims. Third, the claims of Rossling et al. are not limited to fractions below 0.6 (see the above paragraph). Fourth, it is respectfully pointed out that the instant rejection is a 103-obviousness type rejection, wherein the teachings of the reference as a whole are considered, and not just the claims and examples.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is 571-272-0634. The examiner can normally be reached on M&R (5:30-4).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

lqw



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER